

which the PIHP or PAHP is responsible, the rules under this section apply.

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§ 438.116 Solvency standards.

(a) *Requirement for assurances* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO or PIHP, must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PIHP, that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

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Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by

all MCOs, PIHPs, and PAHPs. It also establishes standards that States, MCOs, PIHPs, and PAHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PIHP must do the following:

(a) Have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs.

(b) Obtain the input of beneficiaries and other stakeholders in the development of the strategy and make the strategy available for public comment before adopting it in final.

(c) Ensure that MCOs, PIHPs, and PAHPs comply with standards established by the State, consistent with this subpart.

(d) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy periodically, as needed.

(e) Submit to CMS the following:

(1) A copy of the initial strategy, and a copy of the revised strategy whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following:

(a) The MCO and PIHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures that—

(1) Assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, and to individuals with special health care needs.

(2) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PIHP for each Medicaid enrollee at the time of enrollment.

(3) Regularly monitor and evaluate the MCO and PIHP compliance with the standards.

(c) For MCOs and PIHPs, any national performance measures and levels that may be identified and developed

by CMS in consultation with States and other relevant stakeholders.

(d) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO and PIHP contract.

(e) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

ACCESS STANDARDS

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, and each PIHP and PAHP consistent with the scope of the PIHP's or PAHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO, PIHP, and PAHP must consider the following:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services, taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP.

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, consid-

ering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO or PIHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(c) *Furnishing of services.* The State must ensure that each MCO, PIHP, and PAHP contract complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services.

(ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid fee-for-service, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by providers.